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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,208	09/19/2003	Dennis A. Carson	103.032US1	7161

7590 06/16/2004

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,208	Applicant(s) CARSON ET AL.	
	Examiner Raymond J Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,14 and 15 is/are rejected.
- 7) ☒ Claim(s) 4 and 6-13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed January 22, 2004 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08A (4 pages), the cited references have been considered.

Claim Objections

Claim 9 is objected to because the word "prazocin" is misspelled as "prozosin".

Claims 4 and 6-13 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-3, 5, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prior et al. (U.S. Patent Application Publication No. 2003/0004142, "Prior '142") or Prior et al. (U.S. Patent Application Publication No. 2003/0004143, "Prior '143") in view of Nardella et al. (WO 00/02555, cited by applicants).

Prior '142 and '143 teach methods for treating non-malignant hyperplastic conditions through the inhalation (Prior '142 at page 4, sections [0044]-[0045]) or topical (Prior '143 at page 4, sections [0040]-[0041]) administration of an effective amount of etodolac (see the abstract of each, page 3, fourth line from the end of section [0037] in Prior '142 and page 3, fourth line from the end of section [0034] in Prior '143). In particular Prior '142 teaches precancerous lesions such as hyperplasia, metaplasia and dysplasia (page 5, section [0050]). Prior '143 teaches cervical dysplasias (page 5, section [0050]). Both references teach that the etodolac may be administered along with another chemotherapeutic agent (Prior '142 at page 4, section [0046] and Prior '143 at page 4, section [0044]).

The differences between the above and the claimed subject matter lies in that the references fail to highlight:

(1) a specific instance where etodolac is administered for the purposes taught by the references; and

(2) the administration of the R(-) isomer of etodolac.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) Both references clearly teach that etodolac may be employed in the treatment of the conditions taught and further, both references clearly teach the manner in which the compound is

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to be employed. Given such clear teachings, the skilled artisan would have been motivated by a reasonable expectation of success in doing what the references teach.


(2) the references teach etodolac in general and thus would have encompassed the racemate which would have included the R(-) isomer of etodolac. Moreover, the skilled artisan was well aware that individual isomers of a racemate each possessed differing degrees of activity and the skilled artisan would have been motivated to separate the etodolac isomers in the manner taught by Nardella et al. at page 6, penultimate line so as to determine which of the isomers provided for the most effective therapy.

Accordingly, for the above reasons, the claims are deemed properly objected to/rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

June 15, 2004